DEPARTMENT OF DEFENSE
ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
FALLS CHURCH, VA 22041-3258

REPLY TO
ATTENTION OF

ASBPO (40-2b)

BPL 03-07
30 May 2003

MEMORANDUM FOR SEE DISTRIBUTION

SUBJECT: Revised Policy on Donor Screening, Deferral, and Lookback for West Nile Virus (WNV)

1. The Armed Services Blood Program Office (ASBPO) was established by the Assistant Secretary of Defense for Health Affairs to coordinate the blood programs of the Military Services and the Unified Commands. In that respect, the ASBPO is issuing Blood Program Letter (BPL) 03-07 notifying the Services of the revised policy regarding donor screening, deferral, and lookback for WNV and requiring implementation of nucleic acid WNV testing using investigational procedures. Directions for implementation are contained in enclosure 1. This BPL rescinds previous guidance provided in BPL 02-03, 20 November 2002.

2. In an effort to mitigate the risk that WNV may be transmitted by transfusion, the U. S. Food and Drug Administration (FDA) issued Final Guidance for Industry, *Revised Recommendations for the Assessment of Donor Suitability and Blood Product Safety in Cases of Known or Suspected West Nile Virus Infection* on 1 May 2003, revising guidelines for blood donor screening, deferrals, product quarantine and retrieval, and lookback for WNV, (enclosure 2). The FDA recommends deferring potential donors with possible symptoms of WNV in the 7 days preceding donation and provides recommendations for donor deferral and product management for post-donation illnesses and WNV infection in transfusion recipients. The FDA also recommends the use of donor screening tests to detect acute donor WNV infections once such tests are available.

3. The American Red Cross (ARC) and other independent blood centers associated with the America's Blood Centers (ABC) are prepared to begin blood donor screening for WNV using the Nucleic Acid Test (NAT) methodology on July 1, 2003. Although the nucleic acid test for WNV in blood donors is still investigational and not licensed by the FDA, the FDA is allowing widespread implementation of these tests using investigational procedures. When implemented, approximately 90 percent of the nation's blood supply will be released for transfusion based on WNV NAT results. At that time, WNV NAT will become the standard of care for the industry, even if not yet required by the FDA or performed using a licensed test.

4. Therefore, the Army, Navy, and Air Force Blood Programs will implement nucleic acid testing for WNV under investigational procedures, either by performing the test in-house or by contracting with a laboratory performing the testing. Testing should be implemented to meet projected availability of 24-48 hour turnaround times so that all products can be released based on WNV NAT results. Services must ensure that WNV NAT results are entered into the Defense Blood Standard System (DBSS) to complete the testing record for the donation. Positive WNV NAT results will require quarantine and retrieval of donated components, application of donor deferrals, and may also

include donor and recipient lookback investigations.

5. Until the availability of WNV testing, there will continue to be a risk of transfusion-transmitted WNV infection. The American Association of Blood Banks (AABB) issued *Associated Bulletin #03-04, Mitigating the Risk of Transmission of Human West Nile Virus* on 17 April 2003, (enclosure 3). The AABB provided additional information on WNV risk estimation, patient medical conditions at highest risk for WNV infection, and emphasized that the lifesaving benefits of medically necessary transfusions offset the risk of transfusion-transmitted WNV infection. The clinical information in enclosure 3 should be used to educate clinicians and medical staff about transfusion risks associated with WNV and possible patient options to limit non-urgent transfusions. Services medical treatment facilities may also wish to evaluate their informed consent for transfusion and determine if modifications for WNV risk is necessary.

6. In the event that human cases of WNV occur in a geographical area before WNV testing becomes available, stockpiles of frozen plasma and cryoprecipitate collected before the outbreak should be used in lieu of producing frozen components in areas with human WNV activity. It does not appear feasible to discontinue collection of red blood cells and platelets in large areas experiencing human WNV infection; however, Services may explore options to adjust collection plans within those areas, where feasible.

7. Nucleic acid WNV testing should be implemented as soon as the investigational WNV test is available for widespread use. All other requirements in this policy are effective immediately and should be implemented by 1 June 2003 or as soon as feasible. This policy applies to all Service blood donor centers and medical treatment facilities in CONUS and overseas and should be communicated to appropriate commanders, health care providers, and others involved in its implementation.

8. **Service Blood Program Officers and Combatant Command Joint Blood Program Officers** must complete the enclosed form, *Acknowledgment of Receipt and Implementation*, (Enclosure 4) and return the signed original or fax copy to the ASBPO **NLT 15 June 2003.** A copy of all Service policy documents/letters implementing this BPL must also be forwarded to the ASBPO within 30 days of implementation. The ASBPO point of contact for this action is Lt Col Ruth Sylvester. She can be reached at DSN 761-8011/8024, commercial (703) 681-8011/8024, or via e-mail at ruth.sylvester@otsg.amedd.army.mil.

G. Michael Fitzpatrick

G. MICHAEL FITZPATRICK
COL, USA, MSC
Director

4 Enclosures
as stated

ASBPO (40-2b) BPL 03-07

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ARMED SERVICES BLOOD PROGRAM OFFICE
5109 LEESBURG PIKE
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703-681-8024/8025

ACKNOWLEDGMENT OF RECEIPT AND IMPLEMENTATION

Service Blood Program Officers and Combatant Command JBPOs only: Complete this Acknowledgment of Receipt and Implementation and retain one copy in your file. Return the signed original or fax copy to the Armed Services Blood Program Office
NLT 15 June 2003.

BPL 03-07

Revised Policy on Donor Screening, Deferral, and Lookback for West Nile Virus

30 May 2003

The document listed above was received and the policy implemented by:

SERVICE/UNIFIED COMMAND:_____

DATE RECEIVED:_____

DATE IMPLEMENTED/OR:_____
PROJECTED IMPLEMENTATION

SIGNATURE:_____

NAME/TITLE:_____

For ASBPO use only
Date Returned:_____

Enclosure 4